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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,833	10/24/2003	Marcel Limousin	8707-2165	1007

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Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103

EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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08/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary

Application No.

10/693,833

Applicant(s)

LIMOUSIN ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 15, 2006 have been fully considered but they are not persuasive.

The Applicant argues "Street et al. does not disclose any functionality or structure for using the data acquired during monitoring to actually treat the periodic breathing episodes". However, the pending claims do not recite the "functionality or structure for using the data acquired during monitoring to actually treat the periodic breathing episodes".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "to treat a detected apnea or hypopnea". The specification does not describe treatment of a detected apnea or hypopnea episodes. The specification discloses a means for modifying parameters, not means for treating apnea or hypopnea.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 and 11-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Street et al. (EP 1 151 718 A2). Street et al. discloses an implantable monitor that senses one or more physiologic signals to identify breathing patterns. The physiological signals are processed to generate respiratory rate, respiratory tidal volume, heart rate, or arterial oxygen saturation. The physiologic parameter data are analyzed to derive an indication of periodic breathing and to determine cycles of hypopnic breathing within a periodic breathing episode (col. 4-5, paragraph 19), with the periodic breathing episode itself being apnea. Street et al. further teach that an intracardiac electrogram can be sensed, and heartbeat R-R intervals are calculated, and changes in the frequency of the power spectrum of the signals are used to indicate periodic breathing (col. 6, paragraph 24). Street et al. additionally teach that the status of a patient with chronic heart failure is monitored to optimize patient therapy and to recognize and facilitate the early termination of a developing exacerbation (col. 4, paragraphs 16-17).

Furthermore, as to claim 1, Street et al. discloses in col. 4, paragraphs 16 and 17, "another object of the invention is to monitor the status of a patient with chronic heart failure in order to optimize patient therapy" as well as "recognize and facilitate the

early termination of a developing exacerbation". Therefore, Street et al. does "treat a detected apnea or hypopnea when said detected contractility variation is significant".

As to claims 2 and 3, Street et al. teach that the contractility variation is analyzed before and after detection of hypopnea (figure 2).

As to claim 4, Street et al. teach measuring intrathoracic impedance, and that it can be measured between two cardiac electrodes (col. 4-5, paragraph 14 and paragraph 19).

As to claim 5, Street et al. teach that an electrogram signal is sensed from a sensing electrode, and R-R intervals are calculated and a power spectrum analysis is performed. Changes in the very low frequency component of a power spectrum of R-R intervals are used to indicate periodic breathing (col. 6, paragraph 24).

As to claims 11-13, the apparatus detects cyclic behavior in any of the four physiologic parameters with simple comparisons of present value to programmed thresholds. Thresholds are determined as percentages of the long-term average for that measure (figure 2 and col. 7, paragraph 29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. Claims 9-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. (EP 1 151 718 A2). Street et al. disclose the claimed invention except for the shortened atrio-ventricular delay and multisite pacing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus for treating apnea or hypopnea as taught by Street et al., with a shortened atrio-ventricular delay and multisite pacing since it was known that shortening the atrio-ventricular delay will provide increased metabolic need when the patient requires it and multisite pacing provides a more coordinate therapy to increase cardiac output and treat abnormal cardiac activity.

2. Claims 6-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. (EP 1 151 718 A2) in view of Hartley et al (US 6,161,042). Street et al. teach the apparatus described above, but do not teach modifying the parameter to a second value or restoring the operating value to the first parameter when the analysis means no longer detects a variation. With regards to claims 6, Hartley et al. teach that the minute ventilation short term and long term averages are calculated and compared by subtracting the long term average from the short term average. The difference is optionally scaled and used to adjust the pacing rate by increasing it when the short term average exceeds the long term average (see column 16, lines 20-25). Further, with reference to claim 7, Hartley et al. teach a lower rate limit to which the incremental sensor driven rate is added, and that the minute ventilation indicated rate is the rate at which pacing is delivered. If the value of the short term average is less than the value of the long term average, pacing therapy is delivered at the lower rate limit (see column

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16, lines 30-39). Further, Hartley et al. teach that the minute ventilation is calculated from the transthoracic impedance (see column 6, lines 30-34). Hartley et al. teach that this adjustment of the pacing rate effectively manages the patient's heart rate based on an accurate indication of metabolic need (see column 4, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was disclosed to combine the apparatus taught by Street et al. with the adjustment of pacing rate based upon minute ventilation as taught by Hartley et al. in order to effectively manage the patient's heart rate based on an accurate indication of metabolic need.

3. Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. (EP 1 151 718 A2) in view of Bonnet (US 6,574,507). Street et al. teach the apparatus described above, but do not teach an increase in response to a detected variation and a detected apnea. Bonnet teaches applying an increased cardiac stimulation rate in the event of a detection of an apnea (see column 3, lines 1-3). Bonnet further teaches that apnea is determined in response to a measured respiratory signal that includes a minute ventilation sensor (see column 2, lines 64-66 and column 3, lines 5-6) and further that the minute ventilation parameter is obtained by a measurement of the intrathoracic impedance (see column 4, lines 1-5). Bonnet teaches that increasing the stimulation frequency accelerates the frequency of the myocardium to compensate for the effects of the apnea (see column 8, lines 66-67 and column 9, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the apparatus for treating apnea or

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hypopnea as taught by Street et al. with the increase in frequency stimulation taught by Bonnet in order to accelerate the frequency of the myocardium to compensate for the effects of the apnea.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762


GEORGE R. EVANISKO
PRIMARY EXAMINER
4/13/7